



**[Billing Code 4140-01-P]**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Prospective Grant of Start-Up Exclusive Patent License Agreement:** Treatment of Inflammatory Bowel Disease (IBD), including Ulcerative Colitis and Crohn's Disease

**AGENCY:** National Institutes of Health, HHS.

**ACTION:** Notice.

**SUMMARY:** This is notice, in accordance with 35 U.S.C. 209 and 37 CFR part 404, that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of a Start-Up Exclusive Patent License Agreement to Paris Therapeutics, a company having a place of business in Santee, CA, to practice the inventions embodied in the following patent applications:

1. U.S. Provisional Patent Application. No. 61/488,671, filed 20 May 2011  
HHS Ref. No.: E-073-2011/0-US-01  
Titled: Blockade of TL1A-DR3 Interactions to Ameliorate T Cell Mediated Disease Pathology and Antibodies Thereof  
Inventors: Richard Siegel (NIAMS), Francoise Meylan (NIAMS), and Yun-Jeong Song (NIAMS)
2. PCT Application No. PCT/US2012/028926, filed 13 March 2012  
HHS Ref. No.: E-073-2011/1-PCT-02  
Titled: Blockade of TL1A-DR3 Interactions to Ameliorate T Cell Mediated Disease Pathology and Antibodies Thereof  
Inventors: Richard Siegel (NIAMS), Francoise Meylan (NIAMS), and Yun-Jeong Song (NIAMS)

3. U.S. Patent Application No. 13/419,203, filed 13 March 2012  
HHS Ref. No.: E-073-2011/1-US-01  
Titled: Blockade of TL1A-DR3 Interactions to Ameliorate T Cell Mediated Disease Pathology and Antibodies Thereof  
Inventors: Richard Siegel (NIAMS), Francoise Meylan (NIAMS), and Yun-Jeong Song (NIAMS)
4. Australian Patent Application claiming priority to PCT/US2012/028926, application number not available at this time, filed 26 November 2013  
HHS Ref. No.: E-073-2011/1-AU-03  
Titled: Blockade of TL1A-DR3 Interactions to Ameliorate T Cell Mediated Disease Pathology and Antibodies Thereof  
Inventors: Richard Siegel (NIAMS), Francoise Meylan (NIAMS), and Yun-Jeong Song (NIAMS)
5. Canadian Patent Application claiming priority to PCT/US2012/028926, application number not available at this time, filed 19 November 2013  
HHS Ref. No.: E-073-2011/1-CA-04  
Titled: Blockade of TL1A-DR3 Interactions to Ameliorate T Cell Mediated Disease Pathology and Antibodies Thereof  
Inventors: Richard Siegel (NIAMS), Francoise Meylan (NIAMS), and Yun-Jeong Song (NIAMS)
6. European Patent Application No. 12790157.7, filed 14 November 2013  
HHS Ref. No.: E-073-2011/1-EP-05  
Titled: Blockade of TL1A-DR3 Interactions to Ameliorate T Cell Mediated Disease Pathology and Antibodies Thereof  
Inventors: Richard Siegel (NIAMS), Francoise Meylan (NIAMS), and Yun-Jeong Song (NIAMS)
7. Japanese Patent Application claiming priority to PCT/US2012/028926, application number not available at this time, filed 20 November 2013  
HHS Ref. No.: E-073-2011/1-JP-06  
Titled: Blockade of TL1A-DR3 Interactions to Ameliorate T Cell Mediated Disease Pathology and Antibodies Thereof  
Inventors: Richard Siegel (NIAMS), Francoise Meylan (NIAMS), and Yun-Jeong Song (NIAMS)
8. Korean Patent Application claiming priority to PCT/US2012/028926, application number not available at this time, filed 18 December 2013  
HHS Ref. No.: E-073-2011/1-KR-07  
Titled: Blockade of TL1A-DR3 Interactions to Ameliorate T Cell Mediated Disease Pathology and Antibodies Thereof  
Inventors: Richard Siegel (NIAMS), Francoise Meylan (NIAMS), and Yun-Jeong Song (NIAMS)

9. Mexican Patent Application No. MX/a/2013/013329, filed 14 November 2013  
HHS Ref. No.: E-073-2011/1-MX-08  
Titled: Blockade of TL1A-DR3 Interactions to Ameliorate T Cell Mediated Disease Pathology and Antibodies Thereof  
Inventors: Richard Siegel (NIAMS), Francoise Meylan (NIAMS), and Yun-Jeong Song (NIAMS)
10. U.S. Provisional Patent Application No. 60/879,668, filed 10 January 2007, now expired, HHS Ref. No.: E-011-2007/0-US-01  
Titled: Blockade of TL1A-DR3 Interactions to Ameliorate T Cell Mediated Disease Pathology  
Inventors: Richard Siegel (NIAMS) and Francoise Meylan (NIAMS)
11. U.S. Patent Application No. 11/972,395, filed 10 January 2008, now abandoned, HHS Ref. No.: E-011-2007/0-US-02  
Titled: Blockade of TL1A-DR3 Interactions to Ameliorate T Cell Mediated Disease Pathology  
Inventors: Richard Siegel (NIAMS) and Francoise Meylan (NIAMS)

The patent rights in these inventions have been assigned to the Government of the United States of America. The territory of the prospective Start-Up Exclusive Patent License Agreement may be worldwide, and the field of use may be limited to “Antibodies against TL1A for the Treatment of Inflammatory Bowel Disease (IBD), including Ulcerative Colitis and Crohn’s Disease.”

**DATES:** Only written comments and/or applications for a license which are received by the NIH Office of Technology Transfer on or before [INSERT DATE 15 DAYS FROM DATE OF PUBLICATION OF NOTICE IN THE FEDERAL REGISTER] will be considered.

**ADDRESSES:** Requests for copies of the patent application(s), inquiries, comments, and other materials relating to the contemplated Start-Up Exclusive Patent License

Agreement should be directed to: Jaime M. Greene, M.S., Licensing and Patenting Manager, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; Telephone: (301) 435-5559; Facsimile: (301) 402-0220; E-mail: [greenajaime@mail.nih.gov](mailto:greenajaime@mail.nih.gov). A signed confidentiality nondisclosure agreement will be required to receive copies of any patent applications that have not been published or issued by the United States Patent and Trademark Office or the World Intellectual Property Organization.

**SUPPLEMENTARY INFORMATION:** This technology concerns anti-mouse TNF family ligand Tumor Necrosis Factor (ligand) Superfamily, Member 15 (TL1A) and anti-human TL1A monoclonal antibodies and the hybridoma cell lines generating these antibodies, as well as methods of treating autoimmune inflammatory diseases by blocking the interaction between TL1A and Tumor Necrosis Factor Receptor superfamily, Member 25 (DR3). This technology may be useful for the development of diagnostics and therapeutics for autoimmune inflammatory disease.

The prospective Start-Up Exclusive Patent License Agreement is being considered under the small business initiative launched on October 1, 2011 and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR part 404. The prospective Start-Up Exclusive Patent License Agreement may be granted unless the NIH receives written evidence and argument, within fifteen (15) days from the date of this published notice, that establishes that the grant of the contemplated Start-Up Exclusive Patent License Agreement would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR part 404.

Complete applications for a license in the prospective field of use that are filed in response to this notice will be treated as objections to the grant of the contemplated Start-Up Exclusive Patent License Agreement. Comments and objections submitted to this notice will not be made available for public inspection and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Dated: January 9, 2014.      Richard U. Rodriguez,  
Director,  
Division of Technology Development and Transfer,  
Office of Technology Transfer,  
National Institutes of Health.

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